

### **AMENDMENTS TO THE CLAIMS**

This listing of claims will replace all prior versions and listings of claims in the application.

#### **Listing of Claims:**

Claim 1 (Currently Amended): A method of implanting a bulking device beneath the mucosa in the lower esophagus, comprising the steps of:

- puncturing the mucosa with a device having a first cross sectional area;
- creating a pocket beneath the mucosa and in communication with the puncture;
- enlarging the puncture; and
- introducing a bulking device through the enlarged puncture and into the pocket.

Claim 2 (Original): A method of implanting a bulking device as in Claim 1, wherein the introducing step comprises introducing an expandable bulking device.

Claim 3 (Original): A method of implanting a bulking device as in Claim 2, wherein the bulking device is expandable from an introduction cross sectional area to an enlarged cross sectional area, and the introduction cross sectional area is greater than the first cross sectional area.

Claim 4 (Original): A method of implanting a bulking device as in Claim 1, wherein the introducing step comprises introducing a hydrogel bulking device.

Claim 5 (Original): A method of implanting a bulking device as in Claim 1, wherein the creating a pocket step comprises introducing a volume of fluid beneath the mucosa.

Claim 6 (Original): A method of implanting a bulking device as in Claim 5, wherein the creating a pocket step comprises introducing within the range of from about 0.5 cc to about 5 cc of fluid beneath the mucosa.

Claim 7 (Original): A method of implanting a bulking device as in Claim 5, wherein the fluid comprises saline.

Claim 8 (Original): A method of implanting a bulking device as in Claim 5, wherein the fluid comprises an additive selected from the group consisting of hyaluronic acid, lidocaine, epinephrine, antibiotics, polyethylene glycol, colorants, and contrast media.

Claim 9 (Original): A method of implanting a bulking device as in Claim 5, wherein the introducing a volume of fluid is accomplished using an injection needle.

Claim 10 (Original): A method of implanting a bulking device as in Claim 9, wherein the needle is within the range of from about 18 gauge to about 30 gauge.

Claim 11 (Original): A method of implanting a bulking device as in Claim 1, wherein the enlarging step comprises introducing a dilator through the puncture.

Claim 12 (Original): A method of implanting a bulking device as in Claim 11, wherein the dilator removably carries an introducer sheath.

Claim 13 (Original): A method of implanting a bulking device as in Claim 12, further comprising the steps of removing the dilator from the introducer sheath and introducing the bulking device through the introducer sheath and into the pocket.

Claim 14 (Currently Amended): A method of treating a condition in the lower esophagus, comprising the steps of:

- creating a pocket beneath the mucosa in the lower esophagus; and
- positioning an expandable hydrogel bulking device within the pocket.

Claim 15 (Canceled).

Claim 16 (Original): A method as in Claim 14, wherein the bulking device is expandable in response to exposure to fluid.

Claim 17 (Original): A method as in Claim 15, wherein the bulking device has a diameter prior to implantation within the range of from about 0.2 mm to about 5 mm.

Claim 18 (Original): A method as in Claim 17, wherein the bulking device has a cross section prior to implantation of no more than about 2.5 mm.

Claim 19 (Original): A method as in Claim 14, further comprising the step of removing the bulking device from the pocket.

Claim 20 (Original): A method as in Claim 19, wherein the removing step is accomplished by creating a passageway through tissue to the bulking device.

Claim 21 (Original): A method as in Claim 20, wherein the removing step further comprises using suction.

Claim 22 (Original): A method as in Claim 19, wherein the removing step comprises introducing a solvent to dissolve the bulking device.

Claim 23 (Original): A method as in Claim 22, wherein the solvent comprises DMSO.

Claim 24 (Original): A method as in Claim 19, wherein the removing step is accomplished utilizing a laser.

Claim 25 (Original): A method as in Claim 19, wherein the removing step is accomplished using an energy source.

Claim 26 (Original): A method as in Claim 19, wherein the removing step comprises cutting the bulking device into pieces.

Claim 27 (Currently Amended): A method of explanting a bulking device positioned beneath the mucosa in the vicinity of the lower esophageal sphincter, comprising the steps of :  
locating a solid bulking device positioned beneath the esophageal mucosa;  
~~establishing a passage using a cutting tool to create a tunnel~~ through the mucosa; and  
~~explanting applying a force to explant the~~ solid bulking device through the ~~passage~~ tunnel.

Claim 28 (Currently Amended): A method of explanting a bulking device as in Claim 27 31, wherein the ~~explanting applying a force~~ step is accomplished using an endoscope.

Claim 29 (Canceled).

Claim 30 (Canceled).

Claim 31 (Currently Amended): A method of explanting a bulking device as in Claim 27, wherein the ~~explanting~~ applying a force step is accomplished by applying suction.

Claim 32 (Currently Amended): A method of explanting a bulking device as in Claim 27, wherein the ~~explanting~~ applying a force step comprises pushing the bulking device through the passage.

Claim 33 (Canceled).

Claim 34 (Currently Amended): A method of implanting a bulking device beneath the mucosa in the lower esophagus, comprising the steps of:

puncturing the mucosa with a device having a first cross sectional area;  
enlarging the puncture; and  
introducing an expandable bulking device through the enlarged puncture to a position beneath the mucosa.

Claim 35 (Original): A method of implanting a bulking device as in Claim 34 wherein the introducing step comprises introducing a hydrogel bulking device.

Claim 36 (Original): A method of implanting a bulking device as in Claim 34, wherein the enlarging step comprises advancing a dilator through the puncture.

Claim 37 (Original): A method of implanting a bulking device as in Claim 36, further comprising the steps of advancing a tube through the enlarged puncture and introducing the bulking device through the tube.